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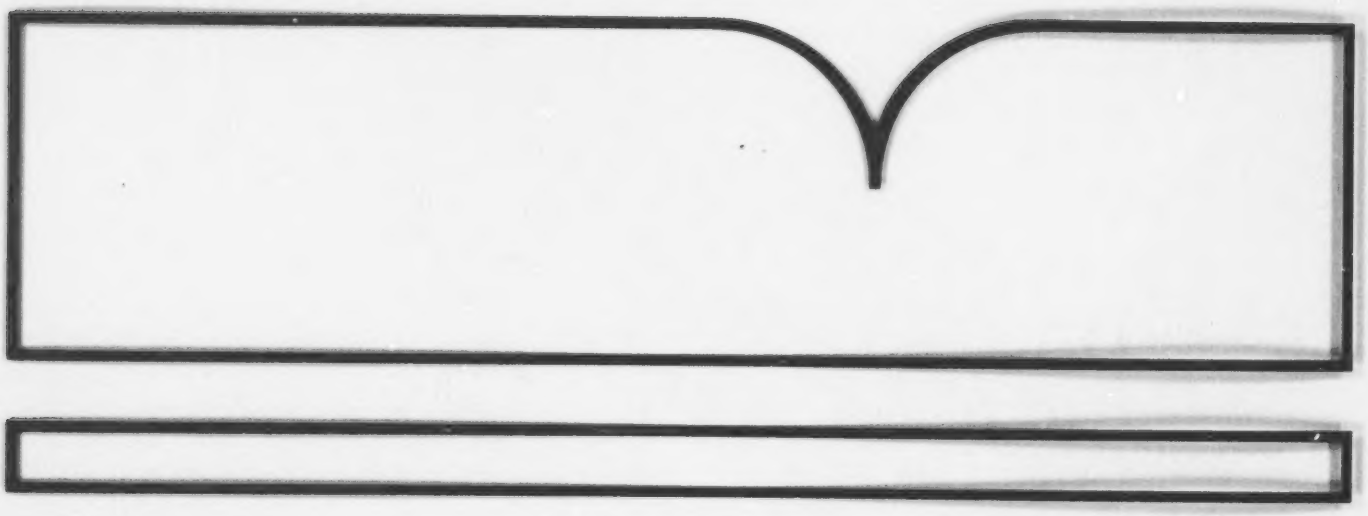

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HAZARD EVALUATION DIVISION

STANDARD EVALUATION PROCEDURE

MAGNITUDE OF THE RESIDUE:

PROCESSED FOOD/FEED STUDIES

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"This Standard Evaluation Procedure (SEP) is one of a set of guidance documents to aid EPA chemists in the evaluation of scientific data submitted pursuant to establishment of pesticide and food/feed additive tolerances. Whenever there is a possibility that residues levels in processed foods/feeds may exceed the levels in the raw agricultural commodities from which they are derived, processing data are required [40 CFR 158.125]. This SEP explains in a detailed, stepwise fashion how EPA data reviewers evaluate processed food/feed studies, and what type information is taken into consideration in the review process."

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STANDARD EVALUATION PROCEDURE

PREAMBLE

This Standard Evaluation Procedure (SEP) is one of a set of guidance documents which explain the procedures used to evaluate environmental and human health effects data submitted to the Office of Pesticide Programs. The SEPs are designed to ensure comprehensive and consistent treatment of major scientific topics in these reviews and to provide interpretive policy guidance where appropriate. The Standard Evaluation Procedures will be used in conjunction with the appropriate Pesticide Assessment Guidelines and other Agency Guidelines. While the documents were developed to explain specifically the principles of scientific evaluation within the Office of Pesticide Programs, they may also be used by other offices in the Agency in the evaluation of studies and scientific data. The Standard Evaluation Procedures will also serve as valuable internal reference documents and will inform the public and regulated community of important considerations in the evaluation of test data for determining chemical hazards. I believe the SEPs will improve both the quality of science within EPA and, in conjunction with the Pesticide Assessment Guidelines, will lead to more effective use of both public and private resources.

Anne L. Barton, Acting Director
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MAGNITUDE OF THE RESIDUE: PROCESSED FOOD/FEED STUDIES

I. INTRODUCTION

A. Purpose of the Standard Evaluation Procedure

This Standard Evaluation Procedure is designed to aid Residue Chemistry Branch (RCB) data reviewers in their evaluations of processed food/feed studies submitted by petitioners/registrants. This particular Standard Evaluation Procedure document addresses processed food and feed commodities, and is intended to be an adjunct to the Standard Evaluation Procedure on Magnitude of the Residue: Crop Field Trials.

B. Background Information

Residue chemistry data on the magnitude of the residue in processed foods/feeds are conditionally required by 40 CFR 158.125 to support the registration of any pesticide intended for use on a food or feed crop under the amended Federal Insecticide, Fungicide, and Rodenticide Act. Specifically, "data on the nature and level of residue in processed food and feed are required when detectable residues could concentrate on processing and thus require establishment of a food additive tolerance."

Residue chemistry data on processed food/feed are used by the Agency to estimate the exposure of the general population to pesticide residues in foods (including animal commodities) and for setting and enforcing food/feed additive tolerances for pesticide residues in or on processed food/feed under provisions of Section 409 of the Federal Food, Drug, and Cosmetic Act. (Note: raw agricultural foods and feeds are regulated under Section 408 of the Act.)

Data on the level of residue in food as consumed are conditionally required under 40 CFR 158.125 when the assumption of tolerance level residues would result in predicted exposure at an unsafe level. Such data are used by the Agency to obtain a more precise estimate of potential dietary exposure.

Residue chemistry data on processed food and feed are also needed to support the adequacy of one or more methods for the enforcement of the food additive tolerance, and to support practical methods (e.g., washing, trimming/peeling, processing, cooking, etc.) for removing residues on food prepared for consumption.

C. Objective of a Processed Food/Feed Study

A processed food/feed study should answer the following question: What is the maximum level of the "total toxic residue" that will likely result in the various processed food/feed commodities resulting from standard (or simulated) commercial processing as compared with the residue level in the raw agricultural commodity from which these processed commodities were prepared (i.e., are concentration factors, if any, ascertainable, or is the processing adequate for estimations of residues in ready-to-eat foods?).

These data are needed to determine whether residues concentrate or are reduced on processing. If residues concentrate, food/feed additive tolerances on the processing fractions containing higher residues than the r.a.c. will be required. If residues are reduced on processing, these data will be used by the Agency as the basis of its estimate of potential dietary exposure. (The tolerance, however, will still be set on the r.a.c. as it travels in interstate commerce.)

The term "total toxic residue" is used to describe the sum of the parent pesticide and its degradation products, metabolites (free or bound), and impurities that are considered to be of toxicological significance, and therefore warrant regulation.

II. INFORMATION TO BE SUPPLIED

The petitioner/registrant's report on the processing of a raw agricultural commodity into its various food/feed components should include all information necessary to provide a complete and accurate description of the raw agricultural commodity (including treatment history and the nature and magnitude of the residue therein); the commercial processing procedure (and, if different, the process used in this study); sample storage; analytical procedure(s) used for residue determinations (including validation data therefor); reporting

of the data and statistical analyses; and, quality control measures/precautions taken to ensure the fidelity of these operations.

A guideline of specific information that should be included in the petitioner/registrant's report of a processing study is provided in the Residue Chemistry Branch Data Reporting Guideline on the Magnitude of the Residue: Processed Food/Feed Studies that complements this Standard Evaluation Procedure. Related information on Crop Field Trials, Storage Stability, and Analytical Method(s), among others, are found in the Standard Evaluation Procedures and Data Reporting Guidelines on those subject areas.

III. THE DATA EVALUATION PROCESS

A. Prepare A Summary

The initial step in the evaluation of processing study data is for the reviewer to carefully examine and summarize the information supplied by the petitioner/registrant in his submission to the Agency. Statistical treatments of the data should be independently verified and the quality control precautions noted.

B. Identify Data Gaps

Using the Pesticide Assessment Guidelines (Subdivision O, Residue Chemistry) Data Reporting Guideline on Magnitude of the Residue: Processed Food/Feed Studies as a guide (in conjunction with the related Guidelines on Crop Field Trials, Storage Stability, and Analytical Method(s), etc.), the reviewer should then look for data gaps--omissions in the information supplied by the petitioner/registrant in his report--and decide which are considered significant enough to adversely affect the review process. Those so identified should be communicated back to the petitioner/registrant by the Product Manager for corrective action.

C. Assess the Appropriateness and Adequacy of the Data

The data reviewer then considers the appropriateness (vis-a-vis the standard commercial processing of the raw agricultural

commodity) and adequacy of the data/information that have been supplied. The aforereferenced Data Reporting Guidelines are a useful guide to the various parameters that need to be considered. Appendix 1 of this document discusses specific aspects of those parameters that warrant consideration.

As an adjunct to these, the reviewer should draw upon the technical guidance in the reviewer aids materials that are available to him, such as the Residue Chemistry Guidelines (a.k.a. Subdivision O of the Pesticide Assessment Guidelines). A listing of some suggested source materials is located in the References section of this document.

Any perceived deficiencies in the data/information supplied should be identified and explained, with a statement as to what steps should be taken to resolve the deficiencies, so that this information can be relayed back to the petitioner/registrant by the Product Manager for appropriate action.

D. Determine the Need for Consultation(s)/Deferrals

In considering the appropriateness and adequacy of the data/information that have been supplied, the data reviewer must also determine if consultation(s)/deferral(s) with/to other HED Branch(es) or Government Agencies (e.g., FDA or USDA) are germane to reaching that decision.

If so, the specific nature of the consultation(s)/deferral(s) should be clearly and succinctly stated to the specific parties whose input is sought.

In the interim period until consultation(s)/deferral(s) are complete, final judgment on the issue(s) in question should be withheld.

E. Conclude if the Requested Action is Supportable

As the last step in the data evaluation process, the data reviewer makes a judgment as to whether the submitted data/information support the requested action (tolerance/registration) of the data submitter.

If the data are not supportive, possible alternative action(s) that may be taken by the petitioner/registrant are suggested.

If deficiencies/omissions exist in the submitted data base, the reviewer may have to defer judgment until such time as appropriate corrective action has been rendered by the petitioner/registrant.

(Note: As stated in (D) above, if consultation(s)/deferral(s) with/to any other HED Branch(es) or Government Agencies are pending, final judgment will need to be held in abeyance until the outcome of such consultation(s)/deferral(s).)

IV. REVIEWER AIDS

There are a large number and variety of source materials that are available to assist the data reviewer in the evaluation process. A listing of some of the more useful references that reside within the Branch is provided in the References section of this document.

APPENDIX I

MAJOR POINTS TO CONSIDER IN EVALUATING FOOD/FEED PROCESSING STUDIES

This Appendix is a supplement to Appendix 1 of the Standard Evaluation Procedure on Magnitude of the Residue: Crop Field Trials. The following are additional specific points to be considered when raw agricultural commodities are normally subjected to commercial processing operations for milled byproducts, oils, pomaces, hulls, etc. that are used as food/feed items.

A. The Raw Agricultural Commodity (r.a.c.)

- Is it clear what the nature and magnitude of the residue were in the r.a.c. samples used in the processing study?
- Are the treatment histories (pesticide(s) used, rate(s), number of applications, PHI's, etc.) of the r.a.c. samples used in the processing study given?
- Did the r.a.c. samples used in the processing study contain field-incurred residues or were they "spiked" with pesticide? (If the latter, see comment in the Pesticide Assessment Guidelines, Subdivision O [Residue Chemistry], p. 21 for the condition under which such fortification may be acceptable.)
- Was the processing study conducted with r.a.c. samples containing detectable residues? At or near the proposed tolerance level? If not, why not? Is the situation correctable?
- Were r.a.c. samples collected at the proposed PHI, or were samples harvested early to ensure adequate field-incurred residues for a processing study?
- Were r.a.c. samples for the processing study field-treated at the intended use rate? An exaggerated rate? If exaggerated, how much so?
- Do exaggerated rate field studies (within the limits of phytotoxicity, etc.) result in a detectable residue in the r.a.c.? If not, is the difference between the analytical limit of detection and the proposed tolerance level greater than the theoretical concentration factor(s)?
- If no detectable residue was in the r.a.c. sample(s) used in the processing study (nor can be achieved because of phytotoxicity considerations), and there is a potential for high theoretical concentration factor(s), is the proposed tolerance supportable?

- Are data provided on theoretical concentration factors? To allow calculation of them? (e.g., % moisture, oil content, etc.)
- Have the r.a.c. samples for use in the processing study been adequately identified?
- Is a commercially important variety of the r.a.c. represented?
- Is it clear what specific plant part(s) were harvested? Processed?
- Have the developmental stage(s) and general condition (e.g., immature/mature, green/ripe, fresh/dry, etc.) of the r.a.c. samples at time of processing been specified?
- Were the r.a.c. samples in any way trimmed, cleaned, or otherwise subjected to a means of residue removal at time of harvest? If so, were the recommended procedures of P.A.M. I, §§141-2 followed?
- Are there livestock or poultry feed items associated with the r.a.c.? Processed commodities? If so, are animal metabolism and feeding studies available?

B. <u>The Processing Procedure</u>

- Has the standard commercial process been identified? Adequately described? Flow diagram(s) provided?
- Does the processing study for the r.a.c. samples in the petitioner/registrant's submission simulate normal commercial practice in the USA? If different, are the differences sufficiently described?
- Are residue data for all processed commodities/byproducts of the r.a.c. provided? (See Table II, Pesticide Assessment Guidelines, Subdivision O [Residue Chemistry].) Residue data presented for pertinent processed commodities/byproducts not identified in Table II?
- If appropriate, are residue data provided on food prepared for consumption?
- Is supplementary processing information available for the pesticide in other reports submitted by the petitioner/registrant on this r.a.c. or botanically related r.a.c.s that can be translated to support the data base, if needed?
- Is the "total toxic residue" altered during processing? If significantly so, has a radiolabeled study been submitted characterizing the nature and extent of the alteration(s)? To validate the enforcement method? (Ref. Pesticide Assessment Guidelines, Subdivision O [Residue Chemistry], p. 21.)

C. Sample Storage

- Is the storage history (e.g., dates, duration, temperature, container type and size, sample weights, etc.) of the r.a.c. samples used for the processing study given?
- How long were processed commodity/byproduct samples stored prior to residue analysis? Are full details of storage conditions, including dates, given?
- In what form (e.g., whole, chopped, as an extract, etc.) were r.a.c. samples stored? Processed commodities/by-products?
- Are storage stability validation data available for the r.a.c. samples used in processing? For the processed commodities/byproducts prepared therefrom?
- What were the means and conditions of shipping the r.a.c. samples to the processing center? To the residue analysis laboratory? Are dates given?
- Has the petitioner provided storage stability data on residues in food prepared for consumption?

D. Analytical Method(s)

- Are the analytical method(s) used in the residue analysis of the processed commodities/byproducts samples for the "total toxic residue" the same as those used to gather residue data on the r.a.c. field trial samples? If not, are differences/modifications identified? Described? Validated? Non-CBI copy available?
- Was more than one analytical method used in the analysis of r.a.c. field trial and processed commodity/byproduct samples for the "total toxic residue" (i.e., a "total" residue method and perhaps separate method(s) for the metabolite(s) of concern)? If so, were each of those method(s) subjected to validation/recovery testing? Limits of detection and sensitivity given for each sample matrix?
- Were the analytical method(s) adequately identified (e.g., title/designation, date and source)?
- Were all the appropriate plant part(s) and processed commodities/byproducts subjected to residue analysis? Identified? (Ref. Table II, Pesticide Assessment Guidelines, Subdivision O [Residue Chemistry].)
- Was any compositing or subsampling done on either the r.a.c. or the processed commodity/byproduct samples at any time? If so, were details given? Were proper sample code numbers maintained?
- Are recovery/validation data available for all the matrices (raw or processed) of interest?

- Are the analytical method(s) used in gathering the residue data the same as those proposed for enforcement? If not, is a paired-test comparison or a method validation needed? Should these method(s) be recommended for inclusion in the PAM?
- Were all the necessary compounds (i.e., those comprising the "total toxic residue") analyzed for in the processed commodities/byproducts? If not, why not?
- In studies involving reduction of residues, are the analytical limits of detection in foods prepared for consumption adequately determined? Defined? Are they different from the r.a.c.? If so, how do they differ?
- Does processing reduce the level of residue to the analytical limit of detection? If so, is the limit of detection low enough for safety evaluation purposes?

E. Residue Results

- Do the residue levels in processed food/feed samples exceed the pesticide residue levels in the r.a.c. samples from which those processed commodities/byproducts were prepared? If so, is the concentration factor clear? Has the petitioner/registrant proposed appropriate food/feed additive tolerance(s)?
- Is a residue reduction indicated in the processed commodity/byproduct samples as compared with those in the r.a.c. from which they were prepared?
- How do these residue results compare with other processing data for this pesticide, if available? If any discrepancies, are these explainable?
- Do the processing study data indicate the need for additional information? Additional analyses? Another study?
- If the petitioner/registrant is proposing food/feed additive tolerance(s) based upon the processing study information submitted, do the results of such studies support the requested action of the petitioner/registrant? If not, what is needed for corrective action?
- If food/feed additive tolerances are being proposed, are they based upon actual concentration factors (from residue analysis of appropriate samples) or upon theoretical (calculated) concentration factors?
- Is there any other unpublished or published information known to us about this pesticide, r.a.c., or the processed commodities/byproducts that must be taken into consideration?
- Are there Codex/FAO Monograph data available for this r.a.c., its processed commodities/byproducts, or botanically related r.a.c.s treated with this same pesticide? If so, are such data being used in the evaluation process?

- Are there international residue limits (IRLs) established for use of this pesticide on this r.a.c.? Its processed commodities/byproducts? If so, upon what use(s) were the IRLs established, and what component(s) of the residue are regulated?
- Can harmonization with any such IRLs be achieved? If not, why not?
- Are the methods of calculating the residue level and percent recovery adequately described (formulae, standard curves, etc.), and illustrated, and the raw data sufficiently detailed so that independent calculations to verify the reported results can be made?
- Were any correction factors (e.g., extraction efficiency, field blanks, etc.) applied to the residue values/recovery values reported?
- If statistical analyses were performed and applied to the results of the residue analysis of the processed commodities/byproducts and the r.a.c.s from which they were derived and/or to the analytical method(s) validation/recovery testing, is sufficient information provided on this to independently validate such calculations?
- Is there a Registration Standard for this pesticide? If so, is it being used in the evaluation of these data?

F. Quality Control

- Are all the raw data reported rather than just average values?
- What quality assurance measures were taken to ensure the fidelity of the residue analyses of the processed commodities/byproducts and the r.a.c.'s from which they were derived? The analytical method(s) validation/recovery testing? Sample storage?
- Are all the significant dates given (e.g., dates of samples receipt in the processing center and laboratory; dates of test substrates preparation [i.e., trimming, chopping, extraction, etc.]; dates of test compounds preparation [i.e., standard reference solutions]; dates of residue analysis, including the determinative step)?
- Was the sample/laboratory coding sufficiently clear so that the history of the r.a.c. sample(s) could be traced from the field, through the processing procedure, through storage, and through residue analysis?
- Were the analytical method(s) validation/recovery test(s) on the processed commodities/byproducts and the r.a.c.s from which they were derived conducted at the same time as the residue analyses of those samples or on different dates? If the latter, what are the respective dates of those operations?

- Is information provided on the equipment/instrumentation used in processing? Storage? Residue analysis? Were these properly calibrated and maintained?
- Were the analyst's worksheets provided? Are they sufficiently detailed?
- Were the person(s) (supervisor, analyst) responsible for the storage, processing, and residue analysis of the residue samples (r.a.c. and the processed commodities/byproducts derived therefrom), including validation/recovery testing, identified (name, title, organization, address, telephone number)?
- Are all the test reports (e.g., storage, processing, residue analyses, validation/recovery testing, etc.) authenticated by appropriate signatures?
- Is a contact person for the petitioner/registrant given with title, address, and telephone number?
- Were representative chromatograms, spectra, etc., as applicable, provided for the residue analyses of the processed commodities/byproducts? The r.a.c.s from which they were derived? Analytical method(s) validation/recovery testing? Storage stability testing?
- Do the representative chromatograms, spectra, etc. indicate adequate clean-up and determination (i.e., low background "noise," adequate signal-to-noise ratio, well-defined peaks rather than shoulder bands, etc.) of the "total toxic residue?"
- Were the storage, residue, and recovery values reasonably uniform for replicate samples?
- Were tests performed for interference from storage containers, reagents, plant matrices, plastic labware, etc.?
- Is information provided on the dates the pesticide reference standard solutions were prepared? How they were stored? How their stability was monitored? How often fresh standard solutions were prepared?

REFERENCES

Following is a listing of some of the more useful source materials within the Residue Chemistry Branch that could prove helpful in reviewing processed food/feed studies:

(1) Foods and Food Production Encyclopedia, D. M. Considine and G. D. Considine, editors, Van Nostrand Reinhold Company, N.Y. (1982);

(2) McGraw-Hill Encyclopedia of Food, Agriculture & Nutrition, 4th ed., D. N. Lapedes, editor-in-chief, McGraw-Hill Book Co., N.Y. (1977);

(3) Soybeans: Improvement, Production, and Uses, B. E. Caldwell, editor, American Society of Agronomy, Inc., Madison, WI (1973);

(4) Fruit and Vegetable Juice Processing Technology, D. K. Fressler and O. J. Maynard, The Avi Publishing Co., Inc., Westport, CT (1961);

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(18) Applications of Absorption Spectroscopy of Organic Compounds, J. R. Dyer, Prentice-Hall, Englewood Cliffs, N.J. (1965);

(19) Systematic Identification of Organic Compounds, R. L. Shriner, et al., John Wiley and Sons, Inc., N.Y. (1965);

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(22) Principles of Radioisotope Methodology, 3rd ed., G. D. Chase and J. L. Rabinowitz, Burgess Publishing Company, Minneapolis, MN (1967);

(23) The Identification of Functional Groups in Organophosphorous Compounds, L. C. Thomas, Academic Press, London, England (1979);

(24) The Pesticide Manual, 7th ed., C. R. Worthing, editor, The British Crop Protection Council, Lavenham Press Limited, Suffolk, England (1983);

(25) EPA Analytical Reference Standards and Supplemental Data, available from the National Technical Information Service, Springfield, VA;

(26) FDA Laboratory Information Bulletins, available from the National Technical Information Service, Springfield, VA;

(27) EPA Manual of Analytical Methods for the Analysis of Pesticides in Humans and Environmental Samples, available from the National Technical Information Service, Springfield, VA;

(28) Chemical Separations and Measurements, D. G. Peters, et al., W. B. Saunders Co., Philadelphia, PA (1974);

(29) Basic Statistics: A Primer for the Biomedical Sciences, O. J. Dunn, John Wiley & Sons, Inc., New York, N.Y. (1964);

(30) Statistical Manual of the Association of Official Analytical Chemists, W. J. Youden and E. H. Steiner, Association of Official Analytical Chemists, Arlington, VA (1975);

(31) Statistical Methods Applied to Experiments in Agriculture and Biology, 7th. ed., G. W. Snedecor, Iowa State College Press, Ames, IA (1980);

(32) Subdivision O (Residue Chemistry) of the Pesticide Assessment Guidelines, §171-3 and §171-4, prepared by OPTS/EPA, Washington, D.C. (1982);

(33) Code of Federal Regulations (40 CFR 158 and 180; 21 CFR 193 and 561), General Services Administration, Washington, D.C., updated annually;

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(41) Farm Chemicals Handbook, Meister Publishing Co., Willoughby, OH, updated annually;

(42) Nanogen Index: A Dictionary of Pesticides and Chemical Pollutants, K. Packer, editor, Nanogens International, Freedom, CA, 1975 (updated periodically by supplements);

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(44) Registration Standards on various individual pesticides, prepared by OPTS/EPA, Washington, D.C. (several issued each fiscal year);

(45) Residue Chemistry Branch files: petition and registration files; reviewer aids; policies; subject files; reading files; et al.;

(46) "The Tolerance Assessment System: Issues," prepared by S. Saunders and S. Johnson, EPA, Washington, D.C., March 7, 1986;

(47) Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater, EPA-600/4-82-057, available from the National Technical Information Service, Springfield, VA (updated periodically);

(48) Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act: Final Rule and Interim Final Rule and Proposed Rule, Federal Register, Vol. 49, No. 209, Friday, October 26, 1984;

(49) Test Methods for Evaluating Solid Waste, EPA SW 846, 2d edition, available from the National Technical Information Service, Springfield, VA (updated periodically);

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